

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 03 January 2001 (03.01.01)	
International application No. PCT/US00/04442	Applicant's or agent's file reference 5274.01
International filing date (day/month/year) 23 February 2000 (23.02.00)	Priority date (day/month/year) 23 February 1999 (23.02.99)
Applicant	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

13 September 2000 (13.09.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38
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PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61K 6/00, 31/04, A01N 33/18, 33/24	A1	(11) International Publication Number: WO 00/49994 (43) International Publication Date: 31 August 2000 (31.08.00)
(21) International Application Number: PCT/US00/04442 (22) International Filing Date: 23 February 2000 (23.02.00) (30) Priority Data: 60/121,430 23 February 1999 (23.02.99) US (71) Applicant (for all designated States except US): DEN-MAT CORPORATION [US/US]; 2727 Skyway Drive, Santa Maria, CA 93455 (US). (72) Inventors: <u>IBSEN, Robert, L.</u> ; 1715 East Marie Street, Santa Maria, CA 93454 (US). <u>MATTHEWS, Alan</u> ; 4306 Foxen Court, Santa Maria, CA 93455 (US). <u>CHADWICK, Thomas, C.</u> ; 496 Alegre Avenue, Nipomo, CA 93444 (US). <u>PINEDA, Rachel</u> ; 927 West Stowell Road, Santa Maria, CA 93458 (US). (74) Agent: RYAN, John, W.; Dorsey & Whitney LLP, Suite 300 South, 1001 Pennsylvania Avenue, N.W., Washington, DC 20004 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>With amended claims.</i>
(54) Title: AN AQUEOUS NON-ALCOHOLIC ORAL RINSE CONTAINING BENZOCAINE AND CARBOMER (57) Abstract A transparent, alcohol-free, aqueous oral rinse composition comprising more than 0.04 % by weight benzocaine, carbomer in an amount that is roughly equal to half the amount of benzocaine employed, and water. The composition relieves the soreness of aphthous ulcers and similar mouth sores.		

FOR THE PURPOSES OF INFORMATION ONLY

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EE	Estonia						

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/04442

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 6/00, 31/04; A01N 33/18, 33/24

US CL :424/401; 514/740, 741, 901

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/401; 514/740, 741, 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X - A	US 5,547,657 A (SINGLETON et al.) 20 August 1996 (20.08.1996), see entire document.	1-3, 10-13 ---- 4-9, 13-20
Y,P	US 5,994,383 A (DYER et al) 30 November 1999 (30.11.1999), column 7, lines 28-46, column 11, lines 53-65, column 14, line 4.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 APRIL 2000

Date of mailing of the international search report

26 APR 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

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Authorized officer
Donna Jagoe
DONNA JAGOE

Telephone No. (703) 308-1235

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/04442

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

West, STN, file registry, adisaletts, adisinsight, aidslite, biobusiness, biosis, cancerlit, caplus, cen, cin, confsci, druglaunch, drugmonog2, drugnl, embal, embase, ifipat, investext, ipa, jicst-eplus, lifesci, medline, napralert, phic, phin, prompt, scisearch, topline. Key words: 94-09-7 (benzocaine), 79-10-7 (acrylic acid), 102-71-6 (triethanolamine), mouth wash, mouth rinse, oral rinse, alcohol free, etoh free, non alcoholic, anesthetic, anaesthetic, local anesthetic.

1	emulsifier	<1.5	
2	flavoring agent	0.001-2	
3	carbomer	>0.08 -10	
4	benzocaine	>0.04 - 5	
5	preservative	<0.05	
6	water	>80	
7	buffering agent	2-5	
8	sweetening agent	0.001-0.25	
9	sodium benzoate	0.05-0.2	
10	weak acid	0.01 - 1	neutralizing agent other than benzocaine
11		0.001 - 3	

12

13 17. The non-alcoholic aqueous oral rinse of claim 12, wherein said rinse

14 comprises the following ingredients in the following amounts:

15	polysorbate	0.12	
16	cocamidopropyl Betaine	0.60	
17	flavoring agent	0.19	
18	carbomer	0.04	
19	benzocaine	0.08	
20	methylparaben	0.12	
21	water	94.10	
22	sodium citrate	2.78	
23	sodium saccharin	0.09	
24	sodium benzoate	0.11	
25	citric acid	0.08	
26	triethanolamine	0.69	

27

1 18. A process for making a non-alcoholic aqueous oral rinse comprising the
2 following steps:

3 (i) dispersing carbomer in aqueous media; and

4 (ii) adding more than 0.04% by weight benzocaine to the media.
5

6 19. The process of claim 18, wherein the ratio of benzocaine to carbomer is
7 approximately 2:1.
8

9 20. The process of claim 15, additionally comprising step (iii), wherein a
10 neutralizing agent other than benzocaine is added to over neutralize the carbomer and form
11 a transparent solution.

PCT

REC'D 26 JUL 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5274.01	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/04442	International filing date (day/month/year) 23 February 2000 (23.02.2000)	Priority date (day/month/year) 23 February 1999 (23.02.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 6/00, 31/04; A01N 33/18, 33/24 and US Cl.: 424/401; 514/740, 741, 901		
Applicant DEN-MAT CORPORATION		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>2</u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 13 September 2000 (13.09.2000)	Date of completion of this report 04 June 2001 (04.06.2001)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer <i>Marianne Cintis</i> Marianne Cintis Telephone No. (703) 308-0193	

I. Basis of the report**1. With regard to the elements of the international application:***☐ the international application as originally filed.☒ the description:

pages 1-10 _____ as originally filed

pages NONE _____, filed with the demandpages NONE _____, filed with the letter of _____☒ the claims:

pages 11-12 _____, as originally filed

pages NONE _____, as amended (together with any statement) under Article 19pages NONE _____, filed with the demandpages 13 and 14 _____, filed with the letter of 03 April 2001 (03.04.2001)☒ the drawings:pages NONE _____, as originally filedpages NONE _____, filed with the demandpages NONE _____, filed with the letter of _____☒ the sequence listing part of the description:pages NONE _____, as originally filedpages NONE _____, filed with the demandpages NONE _____, filed with the letter of _____**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS (Rule 70.7)

Claims 1-20 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an aqueous, non-alcoholic oral rinse solution comprising benzocaine, carbomer and water nor a process for dissolving the benzocaine in the oral rinse by dispersing the carbomer in aqueous media in a ratio of approximately 2:1 to form a transparent solution.

----- NEW CITATIONS -----
NONE

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
31 August 2000 (31.08.2000)

PCT

(10) International Publication Number
WO 00/49994 A1

(51) International Patent Classification⁷: A61K 6/00,
31/04, A01N 33/18, 33/24

(21) International Application Number: PCT/US00/04442

(22) International Filing Date: 23 February 2000 (23.02.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/121,430 23 February 1999 (23.02.1999) US

(71) Applicant (*for all designated States except US*):
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(72) Inventors: IBSEN, Robert, L.; 1715 East Marie Street,
Santa Maria, CA 93454 (US). MATTHEWS, Alan; 4306
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Thomas, C.; 496 Alegre Avenue, Nipomo, CA 93444
(US). PINEDA, Rachel; 927 West Stowell Road, Santa
Maria, CA 93458 (US).

(74) Agent: RYAN, John, W.; Dorsey & Whitney LLP, Suite
300 South, 1001 Pennsylvania Avenue, N.W., Washington,
DC 20004 (US).

(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ,
BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK,
DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL,
IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU,
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RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA,
UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent
(AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent
(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU,
MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— With international search report.

(48) Date of publication of this corrected version:
29 March 2001

(15) Information about Correction:
see PCT Gazette No. 13/2001 of 29 March 2001, Section
II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AN AQUEOUS NON-ALCOHOLIC ORAL RINSE CONTAINING BENZOCAINE AND CARBOMER

(57) Abstract: A transparent, alcohol-free, aqueous oral rinse composition comprising more than 0.04 % by weight benzocaine, carbomer in an amount that is roughly equal to half the amount of benzocaine employed, and water. The composition relieves the soreness of aphthous ulcers and similar mouth sores.

WO 00/49994 A1



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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 5274.01	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US00/04442	International filing date (day/month/year) 23 FEBRUARY 2000	(Earliest) Priority Date (day/month/year) 23 FEBRUARY 1999
Applicant DEN-MAT CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).
2. ☐ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ transcribed by this Authority.
4. With regard to the title, ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - ☒ the text is approved as submitted by the applicant.
 - ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
Figure No. _____
 - ☐ as suggested by the applicant.
 - ☐ because the applicant failed to suggest a figure.
 - ☐ because this figure better characterizes the invention.☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/04442**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61K 6/00, 31/04; A01N 33/18, 33/24

US CL :424/401; 514/740, 741, 901

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/401; 514/740, 741, 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X - A	US 5,547,657 A (SINGLETON et al.) 20 August 1996 (20.08.1996), see entire document.	1-3, 10-13 ---- 4-9, 13-20
Y,P	US 5,994,383 A (DYER et al) 30 November 1999 (30.11.1999), column 7, lines 28-46, column 11, lines 53-65, column 14, line 4.	1-20

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 APRIL 2000

Date of mailing of the international search report

26 APR 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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Washington, D.C. 20231

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/04442

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

West, STN, file registry, adisaletts, adisinsight, aidsline, biobusiness, biosis, cancerlit, caplus, cen, cin, confsci, druglaunch, drugmonog2, drugnl, embal, embase, ifipat, investext, ipa, jicst-eplus, lifesci, medline, napralert, phic, phin, prompt, scisearch, topline. Key words: 94-09-7 (benzocaine), 79-10-7 (acrylic acid), 102-71-6 (triethanolamine), mouth wash, mouth rinse, oral rinse, alcohol free, etoh free, non alcoholic, anesthetic, anaesthetic, local anesthetic.